72-555
No.

IN THE

Supreme Court of The United States

OCTOBER TERM, 1972

ELLIOT L. RICHARDSON, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS

Petitioners

v.

BENTEX PHARMACEUTICALS, INC., ET AL.

Respondents.

RESPONDENTS' BRIEF TO PETITION FOR A WRIT OF CERTIORARI

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COUNTER STATEMENT

The petitioner's statement implies that the jurisdiction of the FDA administratively to adjudicate whether a drug requires an approved new drug application in order to be marketed is related to the issue of whether it is a copy of a drug which has already received such approval.

Under the decision below this relationship is irrelevant. In the present case this relationship is irrelevent, regardless of the theory of law required, since the respondents' products are not "me-too" drugs.

This appeal has arisen prior to the reception of evidence and testimony. Thus the "me-too" status of the respondent's drugs has not been developed in the record. However the fact that the respondent's drugs are not "me-too" drugs is evident.

The Petition (footnote 8, page 6) states that the products subject to NDA withdrawal proceedings were "Nicozol with Reserpine" and "Geroniozol injectible."

The respondent's products differ from the two products for which NDAs were outstanding in that they do not contain reserpine and are orally administered rather than injectibles.[1]

The respondents' products are not copies of Nicozol with Reserpine and Geronizol injectible. This position of the respondents was noted both by the District Court (Petition, page 20a) and the Court of Appeals (Petition, footnote 18, page 9a and 10a), and that the NDA'd products were copies of the respondent's formulation rather than the converse.

The clear inference arises that in fact the two NDA'd products are inferior derivations of the respondents' "pioneer" formulation.

The present case is not an appropriate vehicle for consideration of issues involving "me-too" drugs.

ARGUMENT AGAINST GRANTING THE WRIT

The opinion of the Court below is a full and clear analysis of the Act and supporting authorities. It would be redundant in this argument to repeat the exposition of the Food, Drug and Cosmetic Act contained in that opinion.

The opinion, which is of notable logic and scholarship, arises out of three cases involving the same jurisdictional issue here appealed. These were the present case, *USV Pharmaceutical Corp. v. Richardson,* (461 F. 2d 223) *Hynson, Wescott and Dunning, Inc. v. Richardson,* (Fourth Circuit, No. 72-394, Petition for Certiorari filed September 7, 1972).

In the present case the Court considered the FDA's jurisdiction to pass on the status of drugs which have had no NDA. In the *USV* case the Court considered the jurisdiction of the FDA to pass upon the status of drugs in which an NDA existed. In the *Hynson* case both the manufacturer who held

[1] A preparation of an old drug for administration by novel means requires an approved new drug application. The manner in which a drug is administered has an important bearing on its safety and efficacy.

an NDA, and the FDA, had treated the case as though the FDA had jurisdiction to determine the old drug-new drug status of the product involved, and the Court ruled on the consequences of their position.

These three cases, fully argued and considered, provided the Court below with an invaluable insight into the structure of the Food, Drug and Cosmetic Act. They gave the Court the opportunity to understand the provisions of the Act as an integral whole.

The case of *Ciba-Geigy Corporation v. Richardson* (No. A-249, Third Circuit, Petition for Certiorari being filed on or about October 2, 1972) conflicts with the decision in the present case.

The *Ciba-Geigy* decision is of note primarily for its brevity and for the absence of any cited authority for its conclusions. Its fallaciousness is immediately revealed in the opinion of the Fourth Circuit. The *Bentex* case was decided just prior to the decision of the Third Circuit. Nothing indicates that the Third Circuit considered the analysis contained in the present decision.

The *Ciba-Geigy* case does not constitute a conflict between Courts of Appeal of sufficient import to warrant a review by the United States Supreme Court.

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The Courts have not agreed with the petitioner's statement that application of the definition of a "new drug" turns on "the determination of complex medical and pharmacological questions." (Petition, page 12).

Whether a drug is a "new drug", i.e. not generally recognized among qualified experts as safe and effective, is a question which merely requires the Court to determine the reputation of the drug among qualified experts.

> In such a case as this, the Court does not decide whether the drug is safe and effective; the Court lacks the necessary expertise to make that decision . . . . The question which this Court must decide in this case, with respect to each variation, is whether the

> government has shown by preponderance of the evidence that the 'drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested on the labeling thereof.' U. S. v. . . . . Quickover, 274 F. Supp. 443 (Md. 1967).
>
> Under the statute the question is not whether in point of fact Line Away is unsafe or ineffective. It is whether qualified experts generally recognize Line Away to be unsafe and ineffective for its recommended uses. U. S. v. 36 boxes . . . Line Away, 284 F. Supp. 107 (Del. 1968).

This question is no more difficult than the determination, based on expert testimony, of the relationship of an injury to a disability in a Workman's Compensation case.

The old drug-new drug issue has been commonly determined by summary judgment, based upon affidavits that qualified experts do or do not generally recognize a drug to be safe and effective for its intended uses.

The petitioner concedes that it has no power by administrative action to compel a manufacturer to remove a drug from the market (Petition, page 17).

This can be compelled only by action in a District Court.

The volume of cases of this nature is small. A few cases only are reported each year. The present decision will not add to the case load of the Courts, for the Commissioner has not heretofore exercised the jurisdiction which he now asserts.

As observed by the Court below:

> It is not without significance that, as far as the official reports reflect, the Secretary has never attempted directly to exercise such jurisdiction. The only occasions on which he has sought to assert such jurisdiction has been as an element in his defense to a declaratory judgment action.
> (Petition, pages 12a and 13a).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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